

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant: Kurt-Reiner Geiss

Attorney Docket No.: 7390-X03-018

Application No.: 10/665,394

Confirmation No.: 4213

Filed: September 17, 2003

Group Art Unit: 1612

Examiner: Snigdha Maewall

For: FOOD PRODUCT FOR IMPROVING COGNITIVE FUNCTIONAL
CAPACITY

APPELLANT'S REPLY BRIEF

Board of Patent Appeals and Interferences

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P.O. Box 1450

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Introductory Comments

Sir:

Appellant hereby submits this Reply Brief in accordance with 37 C.F.R. § 41.41 and MPEP §1208. Appellant hereby submits this Reply Brief in further support of the appeal to the Board of Patent Appeals and Interferences from the Examiner's October 14, 2009 final rejection of claims 14, 15, 17-19, and 23-46 of the above-referenced application, as well as in response to the Examiner's Answer mailed August 3, 2010.

I. Status of Claims

The status of the claims remains unchanged since the filing of Appellant's Appeal Brief.

Claims 14, 15, 17-19, and 23-46 are pending.

Claims 14, 15, 17-19, and 23-46 are rejected.

Claims 1-13, 16, and 20-22 are cancelled.

The Appellant is appealing the rejection of independent claims 14, 23, 32, and 43 (and all other remaining claims that depend from these claims). Claims 14, 23, 32, and 43 are on appeal.

II. Grounds of Rejection to be Reviewed on Appeal

Whether claims 14, 15, 17-19, and 23-46 are unpatentable under 35 U.S.C. §103(a) over U.S. Patent No. 6,514,973 B1 to Herwig Buchholz et al. (“Buchholz”) in view of U.S. Patent Application Publication 2003/0161861 A1 to Vincent Lang et al. (“Lang”).

III. Argument

Claims 14, 15, 17-19, and 23-46 are Non-Obvious and Therefore Patentable over Buchholz in view of Lang.

The Examiner maintains her position and continues to assert that the claimed composition and methods are unpatentable because, at the time the invention was made, it would have been obvious to one of ordinary skill in the art to produce the invention by incorporating carbohydrates into the composition of Buchholz because Lang teaches that food products containing carbohydrates improve cognitive performances.

Appellant respectfully disagrees and submits that the Examiner's assertions are insufficient to establish a *prima facie* case of obviousness because a) she fails to evaluate the teachings of Lang as a whole; b) she fails to provide a reasonable suggestion or motivation to combine the teachings of Lang with the teachings of Buchholz; and c) she fails to properly consider the rebuttal evidence in the form of "secondary considerations" as she does not give the Declarations (submitted by the inventor during prosecution) adequate consideration.

By persisting in her argument the Examiner avoids addressing the relevant issue, which is not whether Lang specifically teaches that carbohydrates improve cognitive function, but rather what Lang teaches as a whole, and whether upon consideration of this whole, one of ordinary skill in the art would be led to combine the teachings of Lang with the teachings of Buchholz to produce the claimed invention.

Appellant respectfully submits that the Examiner has not considered Lang as a whole at any time during prosecution of this application.

One cannot establish obviousness by consideration of selective parts of a reference. A proper analysis requires that a reference be considered for everything it teaches by way of technology and is not limited to the particular invention it is alleged to describe. EWP Corp. v. Reliance Universal, Inc. 755 F.2d 898, 225 USPQ 20 (Fed. Cir. 1985).

It is impermissible within the framework of 35 U.S.C. §103 to pick and choose from any one reference only so much of it as will support a given position and ignore the

rest to the exclusion of other parts necessary to the full appreciation of what the reference suggests to one of ordinary skill in the art. Bausch & Lomb, Inc. v. Barnes-Hind Inc. 796 F.2d 443, 230 USPQ 416 (Fed. Cir. 1986).

The Examiner's entire argument is based upon a single teaching of Lang, *i.e.* starch/carbohydrates improve cognitive function. Appellant does not dispute that Lang teaches a composition containing starch which can be useful for improving cognitive function. However, this single teaching does not represent the totality of Lang's disclosure nor does it represent the totality of information it (Lang) would provide to one of ordinary skill in the art regarding carbohydrates and improvement of cognitive function.

Throughout prosecution, Appellant has continuously pointed out teachings of Lang which go beyond the Examiner's single assertion (regarding Lang's teachings), consideration of which are necessary for the proper analysis under 35 U.S.C. §103(a). For example, (1) Lang suggests that glucose may not predictably influence cognitive function, and (2) Lang provides an explicit showing that carbohydrates decrease cognitive functions.

(1) Lang suggests that glucose may not predictably influence cognitive function by first making reference to conflicting data in the art regarding levels of glucose and improvement of cognitive functions, *i.e.* some studies showed glucose influences cognitive functions and some studies showed that glucose did not have a role in cognitive functions (paragraphs [0014]-[0016]), and then including his own observation that regulation of glycemic index alone is insufficient to increase cognitive performances. See paragraph [0017].

(2) In Experimental Example 1, Lang contradicts the results obtained with the claimed composition by demonstrating that foods containing high amounts of simple sugars decrease cognitive function. Lang compares the effects of his composition (biscuits) and commercial ready-to-eat cereals on learning in rats. Although no particular ready-to-eat cereal is identified, the high sugar content of cereals, especially those made for children, is very well known. The results of the comparison showed that the consumption of biscuit is followed by learning which is significantly superior to that

following the consumption of cereals. See paragraphs [0071]-[0075] and Figures 1-2 of Lang.

A prior art reference must be considered in its entirety, i.e. as a whole, including portions that would lead away from the claimed invention. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). See MPEP 2142.02 VI.

While the above-described teachings do not negate Lang's disclosure of a carbohydrate-containing composition which can improve cognitive function, these teachings are encompassed by Lang as a whole and thus, must be considered by the Examiner in a proper analysis of obviousness. Extraction of a single teaching to the exclusion of others is not permitted within the framework of 35 U.S.C. § 103(a).

There is no evidence in the prosecution history that the Examiner has considered any teaching of Lang other than the teaching of carbohydrates for improving cognitive function. Appellant has presented additional teachings of Lang as above at least three times; *i.e.* in the Responses filed on December 19, 2008 and June 12, 2009, and the in Appeal Brief. Since the Examiner has never properly responded to this presentation, it appears that she has either ignored the teachings or deemed them irrelevant. At page 12 of the Examiner's Answer, she states, *inter alia*, the following:

"The reference is considered good for what it teaches...Nowhere in Lang is it stated that carbohydrates do not improve cognitive performance."

Thus, her lack of consideration for Lang as a whole is apparent, since, as described above, Lang not only states, but also demonstrates, that carbohydrates do not improve cognitive performance. See Experimental Example 1 of Lang.

Accordingly, since it is clear that the Examiner has not evaluated Lang as a whole by selecting only the part of Lang's teachings which support her position, Appellant respectfully submits that the Examiner's analysis should not be considered proper or complete under 35 U.S.C. §103(a).

Since the Examiner has failed to consider the whole of Lang, it follows that she relies on an incomplete interpretation of his (Lang's) teachings to support her arguments.

For example, in recanting the teachings of Lang (pages 9-10 of the Examiner's Answer), the Examiner asserts that Lang emphasizes, in paragraph [0022], that slowly-available glucose content is the preferred carbohydrate used in his invention.

Appellant disagrees with this interpretation. Paragraph [0022] states, *inter alia*, the following:

Preferably, the cereal products which can be used according to the invention have a slowly available glucose content relative to the total carbohydrate content... (Emphasis added herein by Appellant).

Thus, in contrast to the Examiner's incomplete interpretation, the emphasis of Lang is on the ratio of slowly-available glucose to the total carbohydrate content of the cereal rather than simply "glucose content."

What a reference teaches is a question of fact. In re Beattie, 974 F.2d 1309, 24 USPQ2d 1040 (Fed. Cir. 1992).

Appellant has pointed out the facts of Lang's teachings in all of the Responses filed during prosecution of this application. The actual teachings of Lang provide a more complex view of the effects of carbohydrates on cognitive function than one would be led to believe from the Examiner's incomplete and oversimplified assertion. Lang does not disclose that foods merely containing "starch", "glucose", or "carbohydrates" are capable of improving cognitive function, but rather discloses a cereal product, having a specific ratio of slowly-digestible starch to total starch content, which is capable of improving cognitive function. The positive effects (on cognitive function) are due to the choice of appropriate ratio and not simply from an inclusion of carbohydrates. This is clearly evident in the experimental examples of Lang wherein he tested his food product against ready-to-eat cereals (Example 1, as described above) that also contained carbohydrates, but did not improve cognitive function.

In addition to a specific ratio of slowly-digestible starch to total starch content, Lang also points to lipid content (of his cereal product) as a contributor to the positive effects on cognitive function demonstrated by his cereal product. For example, Lang showed his product could achieve desired slowing of digestion (of carbohydrates) using

only moderate levels of lipid despite the accepted wisdom that high levels of lipid slow down digestion of carbohydrates. See paragraphs [0018] and [0025] and Table 8 (biscuit composition). This information broadens Lang's disclosure to one of ordinary skill in the art and sheds further doubt on the alleged predictability of the claimed invention.

Based on the above (specific ratio and lipid content), it is clear that Lang's teachings regarding carbohydrates and cognitive function are much broader than simply teaching carbohydrates improve cognitive performances as asserted by the Examiner.

In addition to both the incorrect and incomplete interpretation of the teachings of Lang described above, the Examiner also errs in applying the standards for establishing *prima facie* obviousness as she fails to provide a reasonable suggestion or motivation to combine the teachings of Lang with the teachings of Buchholz.

At page 10 of the Examiner's Answer, she states, *inter alia*, the following:

"...Since Lang teaches utilization of the claimed carbohydrates in substantially similar claimed amounts for the same cognitive improvement and Buchholz teaches improvement of cognitive performance due to phosphatidylserine, one of ordinary skill would have envisaged utilizing the two components together for cognitive functional improvements."

Whether or not a composition improves cognitive function is not the relevant inquiry for ultimately deciding obviousness in this case. The statements that Lang teaches carbohydrates for improvement of cognitive function and Buchholz teaches phosphatidyl serine for improvement of cognitive function are factual statements regarding the teachings of the references. A statement of the teachings (of the references) alone is insufficient to establish obviousness of an invention.

"The question under 35 USC 103 is not merely what the references expressly teach but what they would have suggested to one of ordinary skill in the art at the time the invention was made." In re Lamberti, 545 F.2d at 750, 192 USPQ at 280 CCPA 1976.

The Examiner must explain why the differences in the prior art and the claimed invention would have been obvious to one of ordinary skill in the art. Further, the

Examiner must provide a suggestion and/or motivation to one of ordinary skill in the art which would encourage him/her to combine the teachings of cited references.

Therefore, the relevant inquiry is whether one of ordinary skill in the art would ascertain from Lang that carbohydrates could be added to the composition of Buchholz in the same manner as the carbohydrates of the claimed composition, without any knowledge of the instant specification, to produce the claimed invention. Or, in other words, an Examiner must explain why one of ordinary skill in the art when confronted with the same problems as the inventor, with no knowledge of the invention, would select the elements from the cited prior art for combination in the manner claimed.

First, why would one of ordinary skill in the art look to add carbohydrates to Buchholz's composition when the carbohydrates already present in the composition (Buchholz's) are considered "inactive" ingredients?

Upon reading Lang's disclosure one would ascertain that although regulation of glycemic index alone is insufficient to increase cognitive performance, a product having a specific ratio of slowly-digestible starch to total starch content can improve cognitive performance.

Why would one be encouraged to add carbohydrates when presented with the information that regulation of glycemic index is insufficient to increase cognitive performance? Why would one think to formulate Buchholz's composition with slowly-digestible carbohydrates, especially when Buchholz's composition is disclosed as pills/tablets for oral delivery? Carbohydrates, as disclosed by Lang, are not suitable for inclusion in a pill format.

Without answers to these questions, one of ordinary skill in the art would not have any reason or motivation to combine the teachings of Lang with the teachings of Buchholz. Even if one were to combine these teachings, considering the manner with which Lang formulates addition of carbohydrates, the addition of carbohydrates in the purported combination would not be in the same manner as in the claimed composition as would be required for a proper suggestion or motivation to combine.

Accordingly, based on the above, Appellant respectfully submits that the Examiner has failed to provide a convincing showing of suggestion or motivation to combine the teachings of Lang and Buchholz.

During prosecution Appellant submitted two Declarations under 37 C.F.R. §1.132 signed by the inventor, Dr. Kurt-Reiner Geiss, and filed on December 19, 2008 and June 12, 2009, respectively. The data presented in these Declarations shows a synergistic effect on cognitive functional capacity from the combination of phosphatidyl serine and carbohydrates over the effect of each ingredient alone (*i.e.* phosphatidyl serine alone and carbohydrates alone). Thus, this data constitutes objective evidence of non-obviousness of the claimed invention.

The following remarks are in response to the Examiner's assertions regarding the Declarations at pages 13-17 of the Examiner's Answer.

Independent claims 14, 23, 32, and 43 recite carbohydrates. Dependent claims 17, 26, and 34 recite the specific simple carbohydrates glucose, fructose, and sucrose. The data in the Declarations is neither limited to carbohydrates nor to simple carbohydrates. Thus, the Declarations are commensurate in scope with the pending claims.

At page 14 of the Examiner's Answer, the Examiner asserts "*The declaration provides data for only 200mg of phosphatidyl serine and 20g of carbohydrate and for 150mg phosphatidyl serine and 15g of carbohydrates whereas the claims as recited have the limitation of a minimum of 100mg of phosphatidyl serine and a minimum of 10g carbohydrates, as such no data has been provided for amounts which are below 150mg of phosphatidyl serine and less than 15g of carbohydrates.*"

Appellant disagrees and respectfully points out that this assertion has been addressed multiple times during prosecution. Nevertheless, Appellant addresses it yet again herein.

The claims, as currently pending, recite minimums of about 100mg to 200mg phosphatidyl serine and about 10g to 20g carbohydrates. The subjects participating in the IQPLUS Brain Bar study (experimental example 1 of the Declarations) consumed one bar, one bar including 200mg phosphatidyl serine and 20g of carbohydrates, per day for

the first two weeks of the study. The subjects then consumed a half of a bar for the following twelve weeks. One half of a bar contains 100mg of phosphatidyl serine and 10g of carbohydrates. Therefore, the average consumption per subject was 117mg of phosphatidyl serine and 11.7g of carbohydrates for the duration of the twelve week study. Thus, in contrast to the Examiner's assertion, data has been provided for amounts which are below 150mg of phosphatidyl serine and less than 15g of carbohydrates. Accordingly, the range of amounts of phosphatidyl serine and carbohydrates exemplified in the experimental examples is commensurate with the range of amounts claimed.

Although the claimed range of amounts of phosphatidyl serine and carbohydrates is adequately represented by the data, Appellant notes that results over the entire range of properties is not required and should not be required by Office personnel to establish a sufficient rebuttal of obviousness.

When considering whether proffered evidence is commensurate in scope with the claimed invention, Office personnel should not require the applicant to show unexpected results over the entire range of properties possessed by a chemical compound or composition. See, e.g., In re Chupp, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987). Evidence that the compound or composition possesses superior and unexpected properties in one of a spectrum of common properties can be sufficient to rebut a prima facie case of obviousness. Id. See MPEP 2145.

The Examiner again refers to Figure 3, as presented in the Declarations (page 7 of Exhibit C of the Appeal Brief and page 6 of Exhibit D of the Appeal Brief), as “*showing a standard deviation which is so high that one cannot determine the statistical significance, let alone the palatable significance.*”

Appellant strongly disagrees. Figure 3 represents the results of Experimental Example Two and shows that the golfers who consumed the food bar (combination of phosphatidyl serine and carbohydrates) achieved a greater amount of correct ball flights than did the golfers who consumed carbohydrates alone or phosphatidyl serine alone combined. The combination of phosphatidyl serine and simple carbohydrates resulted in a statistically significant ($p < 0.05$) improvement of good ball flights, which can result with improved golf scores overall for the golfers. See section entitled “Results” at the top of page 6 of Exhibit D of the Appeal Brief. Thus, the statistical significance can be determined. The Examiner's opinion does not overcome the numbers.

Next, the Examiner refers to the experimental data at page 2 of Exhibit C (of the Appeal Brief) and suggests that these results are not relevant because the study only compares subjects who consumed the IQPLUS Brain Bar and subjects who did not consume the IQPLUS Brain Bar and lacks comparison with subjects who consumed carbohydrate alone and phosphatidyl serine alone.

Appellant disagrees. The Examiner refers to results which are part of Experimental Example One. Subjects consuming carbohydrates alone and phosphatidyl serine alone are compared in Experimental Example Two. There is no requirement for each experimental example presented as evidence to evaluate the same questions or to provide the same result.

The Examiner then skips to commenting on Experimental Example Two and asserts *“Results from only 2 subjects consuming PS do not provide any statistical significance. The rationale behind having 10 subjects consuming carbohydrate and only 2 subjects consuming PS is not clear to the Examiner.”*

The rationale for having only two subjects in the phosphatidyl serine group, ten subjects in the carbohydrate group, and ten subjects in the combination (phosphatidyl serine and carbohydrates) group is scientific as well as financial. The phosphatidyl serine group consumed 200mg of phosphatidyl serine. Based upon existing literature, this low amount of phosphatidyl serine was not expected to have any effect on the study parameters. In order to reduce costs for the total study, a smaller sample size in the phosphatidyl serine group was tested as no effect was expected. If even a small effect was found, the sample size for the phosphatidyl serine group would have been increased, but there was no scientific reasoning or effect to justify the additional expenses. Appellant respectfully submits that any actively-practicing scientist would find this rationale acceptable for producing valid results.

The Examiner again concludes that there is “no control to compare with” in the experiments disclosed in the Declarations.

Appellant disagrees. Three groups of data evaluating golf ball flights are shown in Figure 3; one group for subjects consuming phosphatidyl serine alone; a second group for subjects consuming carbohydrates alone; and a third group for subjects consuming the

combination of phosphatidyl serine and simple carbohydrates. At the start, ball flights were measured in order to establish a baseline performance (pre-test). The baseline performance is used for comparison against performance measured after a time period of consuming the assigned food such that any improvements can be determined. Thus, the baseline performance functions as a “control” for the experiment.

The Examiner further states *“Instant claims recite the minimum effective amount for improving cognitive performance to be 100mg, the declaration on page 6 and 7 recognizes that there is no difference in results pre and post test when only phosphatidyl serine or only carbohydrate was consumed, it is unclear to the Examiner how a nutritional bar with a 100mg PS will improve cognitive performance when the one with 200mg does not show any difference in cognitive performance compared to one without any PS.”*

The food/food bar, as currently claimed, comprises a combination of phosphatidyl serine and carbohydrates. The claims do not recite that a 100mg or any amount of phosphatidyl serine alone is effective for improving cognitive function. The results showing no difference in performance pre and post test reflect consumption of phosphatidyl serine alone. The improvement obtained from the food/food bar containing 100mg phosphatidyl serine is due to the combination of phosphatidyl serine and carbohydrates. No comparison is made between a food/food bar containing 100mg phosphatidyl serine alone and a food/food bar containing 200mg phosphatidyl serine alone.

Based on the above, that submitted in the Appeal Brief, and that submitted in the Responses presented during prosecution, Appellant respectfully submits that the Examiner appears to lack understanding of both the claimed invention and the data presented in the Declarations and has failed to adequately consider the data presented in these Declarations at any time during prosecution.

IV. Conclusion of Reply Brief

First, in view of the Examiner's apparent lack of consideration of Appellant's entire response and subsequent repetition of arguments (described above) Appellant asserts that both the claims and the data presented in the Declarations have not been given adequate consideration and thus respectfully requests that the rejection of claims 14, 15, 17-19, and 23-46 be reversed for this reason alone. Regardless, Appellant respectfully submits that the foregoing arguments and those in the Appeal Brief (including all attached Exhibits) sufficiently refute the Examiner's case of obviousness against the claimed composition and methods.

After consideration of all of the above arguments and those presented in the Appeal Brief, it is clear neither Buchholz nor Lang, alone or in combination, teach or suggest a composition, *i.e.* food or food/bar (or method for using the composition) for improving cognitive functional capacity of a consumer of the food/food bar including a minimum of 100 mg to about 200 mg of phosphatidyl serine and a minimum of 10 g to about 20 g of carbohydrates which synergistically interact to produce the improvement in cognitive functional capacity.

Appellant respectfully submits that he has now shown that 1) the combination of Buchholz and Lang does not disclose every feature of the composition or method as claimed; 2) the combination of Buchholz and Lang would not produce the composition or method as claimed; and 3) the prior art provides no reasonable basis for suggestion or motivation to combine the teachings of Buchholz and Lang.

Additionally, Appellant has shown herein that the Examiner's arguments are not sufficient to properly support a *prima facie* case of obviousness because a) she fails to evaluate the teachings of Lang as a whole; b) she fails to provide a reasonable suggestion or motivation to combine the teachings of Lang with the teachings of Buchholz; and c) she fails to properly consider the rebuttal evidence in the form of "secondary considerations" as she does not give the Declarations (submitted by the inventor during prosecution) adequate consideration.

Accordingly, Appellant respectfully submits that independent claims 14, 23, 32, and 43 are non-obvious and therefore patentable over Buchholz in view of Lang.

Accordingly, Appellant respectfully suggests that the rejection of claims 14, 23, 32, and 43 has been overcome and should be withdrawn.

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). See also MPEP 2143.03

As claims 15, 17-19, 37, and 40 depend from claim 14; claims 24-31, 36, 38, and 41 depend from claim 23; claims 33-35, 39, and 42 depend from claim 32; and claims 44-46 depend from claim 43, these dependent claims necessarily include all the elements of their base claims. Thus, Appellant respectfully submits that the dependent claims are allowable over Buchholz in view of Lang at least for the same reasons as the independent claims.

For all of the reasons stated above, in the Appeal Brief, and in the Responses filed during prosecution the Appellant contends that each claim is patentable. Therefore, reversal of the rejection is courteously solicited.

No fee is believed to be due for the filing of this Reply Brief. However, please charge any required fees (or credit any overpayment of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 7390-X03-018).

Respectfully submitted,

Dated: October 4, 2010

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